

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims:

1-89. (canceled)

90. (currently amended) A pharmaceutical dosage form for oral administration to a patient providing pulsed gastric release of methylphenidate comprising:

- a) a gastric retention vehicle composition comprising about 10 wt-% to about 75 wt-% superdisintegrant, about 2 wt-% to about 12 wt-% tannic acid, and about 20 to about 70 wt-% of a hydrogel, whereby the gastric retention vehicle composition ~~includes~~ is a homogenous solid matrix and the percentages are calculated with respect to the matrix exclusive of other excipients and the methylphenidate,
- b) a plurality of first particles containing methylphenidate that are dispersed in the matrix, wherein the methylphenidate is released from the first particles into the stomach upon contact with gastric fluid, and
- c) a plurality of second particles containing methylphenidate that are dispersed in the matrix, wherein each of the second particles is coated with a coating that is impermeable to methylphenidate and dissolves in gastric fluid, and, after a sufficient amount of the coating is dissolved, the methylphenidate is released from the second particles into the stomach,

wherein, upon contact with gastric fluid the gastric retention vehicle composition expands to a sufficient degree such that the dosage form is retained in the stomach at least until methylphenidate is released from the second particles.

91. (previously presented) A pharmaceutical dosage form of claim 90 further comprising a plurality of third particles containing methylphenidate that are dispersed in the matrix, wherein each of the third particles is coated with a coating that is impermeable to the methylphenidate and dissolves in gastric fluid and the methylphenidate is released from the third particles into the stomach after the methylphenidate is released from the second particles.

92. (previously presented) A pharmaceutical dosage form of claim 90 wherein the first

particles are coated with a coating that delays release of the methylphenidate from those particles, with the proviso that the first particles and the second particles are not released at the same time.

93. (currently amended) A pharmaceutical dosage form for oral administration to a patient providing pulsed gastric release of methylphenidate comprising:

- a) a gastric retention vehicle composition comprising about 20 wt-% to about 70 wt-% of a hydrogel, about 10 wt-% to about 75 wt-% superdisintegrant and about 2 wt-% to about 12 wt-% tannic acid, the percentages calculated exclusive of other excipients or the methylphenidate,
- b) a first reservoir containing methylphenidate embedded in said gastric retention vehicle composition wherein methylphenidate is released from the first reservoir into the stomach upon contact of the dosage form with gastric fluid, and
- c) a second reservoir containing methylphenidate embedded in said gastric retention vehicle composition, wherein the second reservoir is coated with a coating that is impermeable to methylphenidate and dissolves in gastric fluid, and, after a sufficient amount of the coating is dissolved, the methylphenidate is released from the second ~~particles~~ reservoir into the stomach,

wherein, upon contact with gastric fluid the gastric retention vehicle composition expands to a sufficient degree such that the dosage form is retained in the stomach at least until methylphenidate is released from the second reservoir.

94. (previously presented) A pharmaceutical dosage form of claim 93 further comprising a third reservoir containing methylphenidate coated with a coating that is impermeable to methylphenidate and dissolves in gastric fluid, wherein the methylphenidate is released from the third reservoir into the stomach after the methylphenidate is released from the second reservoir.

95. (original) A pharmaceutical dosage form of claim 93 wherein the first reservoir is coated with a coating that delays release of the methylphenidate from that reservoir.

96. (original) A pharmaceutical dosage form of claim 93 wherein the gastric retention vehicle composition and the reservoirs are encapsulated.

97-112. (canceled)

113. (previously presented) The pharmaceutical dosage form of claim 90, wherein the methylphenidate is released from the second particles into the stomach about 3 to about 5 hours after administration.

114. (previously presented) The pharmaceutical dosage form of claim 93, wherein the methylphenidate is released from the second reservoir about 3 to about 5 hours after administration.

115. (previously presented) The pharmaceutical dosage form of claim 91, wherein the methylphenidate is released from the third particles into the stomach about 3 to about 5 hours after the methylphenidate is released from the second particles.

116. (previously presented) A method of treating hyperactivity or attention deficit disorder comprising administering a therapeutically effective amount of methylphenidate in the pharmaceutical dosage form of claim 90 to a patient in need thereof.

117. (previously presented) A method of treating hyperactivity or attention deficit disorder comprising administering a therapeutically effective amount of methylphenidate in the pharmaceutical dosage form of claim 93 to a patient in need thereof.

118. (currently amended) The pharmaceutical dosage form of claim 90, wherein the coating comprises (i) a film coating agent selected from the group consisting of water soluble resins, water insoluble resins, waxes, lipids, and enteric resins, ~~or (ii) a polymeric coating substance.~~

119. (previously presented) The pharmaceutical dosage form of claim 93, wherein the coating comprises polymethacrylate, or a mixture of hydrophilic and hydrophobic film forming agents.

120. (currently amended) The pharmaceutical dosage form of claim ~~[[93]]~~ 119, wherein the hydrophilic film forming agent is selected from the group consisting of methyl cellulose, hydroxypropyl methylcellulose, cellulose phthalate, cellulose acetate phthalate, and polyvinyl alcohol.

121. (currently amended) The pharmaceutical dosage form of claim ~~[[93]]~~ 119, wherein the

hydrophobic film forming agent is selected from the group consisting of ethyl cellulose, cellulose acetate, hydroxypropyl methylcellulose phthalate, polyvinyl alcohol maleic anhydride copolymers, β -pinen polymers rosin, partially hydrogenated rosin, and glycerol esters of rosin.

122. (previously presented) The pharmaceutical dosage form of claim 90, wherein the superdisintegrant is selected from the group consisting of cross-linked carboxymethylcellulose sodium, sodium starch glycolate, and cross-linked polyvinyl pyrrolidone.

123. (previously presented) The pharmaceutical dosage form of claim 93, wherein the superdisintegrant is selected from the group consisting of cross-linked carboxymethylcellulose sodium, sodium starch glycolate, and cross-linked polyvinyl pyrrolidone.

124. (previously presented) The pharmaceutical dosage form of claim 90, wherein the hydrogel is hydroxypropyl methyl cellulose or a mixture of hydroxypropyl methyl cellulose and hydroxypropyl cellulose or a cross-linked acrylate polymer.

125. (previously presented) The pharmaceutical dosage form of claim 93, wherein the hydrogel is hydroxypropyl methyl cellulose or a mixture of hydroxypropyl methyl cellulose and hydroxypropyl cellulose or a cross-linked acrylate polymer.

126. (new) The pharmaceutical dosage form of claim 90, comprising from about 30 wt. % to about 55 wt. % superdisintegrant, about 5 wt. % (± 2 wt. %) tannic acid, plus an amount of hydrogel sufficient to bring the total to 100 wt. %.

127. (new) The pharmaceutical dosage form of claim 93, comprising from about 30 wt. % to about 55 wt. % superdisintegrant, about 5 wt. % (± 2 wt. %) tannic acid, plus an amount of hydrogel sufficient to bring the total to 100 wt. %.

128. (new) The pharmaceutical dosage form of claim 90, comprising from about 10 wt. % to about 30 wt. % hydroxypropyl methylcellulose, from about 40 wt. % to about 60 wt. % hydroxypropyl cellulose, and about 4 wt. % to about 12 wt. % tannic acid.

129. (new) The pharmaceutical dosage form of claim 90, comprising from about 10 wt. % to

about 20 wt. % hydroxypropyl methylcellulose, from about 45 wt. % to about 50 wt. % hydroxypropyl cellulose, and about 4 wt. % to about 6 wt. % tannic acid.

130. (new) The pharmaceutical dosage form of claim 93, comprising from about 10 wt. % to about 30 wt. % hydroxypropyl methylcellulose, from about 40 wt. % to about 60 wt. % hydroxypropyl cellulose, and about 4 wt. % to about 12 wt. % tannic acid.

131. (new) The pharmaceutical dosage form of claim 93, comprising from about 10 wt. % to about 20 wt. % hydroxypropyl methylcellulose, from about 45 wt. % to about 50 wt. % hydroxypropyl cellulose, and about 4 wt. % to about 6 wt. % tannic acid.